

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2003/001598

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61K 45/06, A61K 9/00, A61P 1/04 // A61K 31/4439, A61K 31/4164, A61K31/341, A61K31/426

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61K, A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI DATA, EPO-INTERNAL, PAJ, CA DATA, MEDLINE, BIOSIS, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02083132 A1 (DIABACT AB), 24 October 2002 (24.10.2002) --	1-48
Y	US 6183776 A (HELENE DEPUI ET AL), 6 February 2001 (06.02.2001) --	1-48
Y	WO 9725065 A1 (ASTRA AKTIEBOLAG), 17 July 1997 (17.07.1997) --	1-48
Y	WO 9311750 A1 (FUISZ TECHNOLOGIES LTD.), 24 June 1993 (24.06.1993) --	1-48

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document: member of the same patent family

Date of the actual completion of the international search

15 January 2004

Date of mailing of the international search report

22-01-2004

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2003/001598

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	Br. J. Clin. Pharmac., Volume 31, 1991, Tommy Andersson et al: "Influence of acid secretory status on absorption of omeprazole from enteric coated granules", page 275-278  --	1-48
Y	Canadian pharmaceutical journal, Volume 135, no. 7, 2002, Doret Cheng: "Combined use of proton pump inhibitors and histamine-H2 receptor antagonists for GERD: What is the rationale?", page 27 - page 45  --	1-48
Y	Gastroenterology, Volume 115, 1998, Paolo L. Peghini et al: "Ranitidine Controls Nocturnal Gastric Acid Breakthrough on Omeprazole: A Controlled Study in Normal Subjects", page 1335 - page 1339  --	1-48
Y	Baillière's Best Practice & Research Clinical Gastroenterology, Volume 15, no. 3. 2001, Philip O. Katz MD et al: "Histamine receptor antagonists, proton pump inhibitors and their combination in the treatment of gastro-oesophageal reflux disease", page 371 - page 384  --	1-48
A	US 5204118 A (WILLIAM J. GOLDMAN ET AL), 20 April 1993 (20.04.1993)  --	1-48
A	WO 9904773 A2 (MERCK & CO., INC.), 4 February 1999 (04.02.1999)  -----	1-48

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01/12/2003

International application No.

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01/12/2003

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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE03/01598

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 40-48  
because they relate to subject matter not required to be searched by this Authority, namely:  
**see next sheet\***
2. ☒ Claims Nos.: 1-39  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
**see next sheet\*\***
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (January 2004)

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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/SE03/01598

Box No. IV Text of the abstract (Continuation of Item 5 of the first sheet)

\*

Claims 40-48 relate to methods of treatment of the human or animal body by surgery or by therapy or diagnostic methods practised on the human or animal body (PCT Rule 39.1(iv)). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds or compositions.

\*\*

Present claims 1-39 relate to dosage forms, and to methods for the production of these dosage forms, defined by reference to desirable properties of the dosage forms, namely "inhibition of acid susceptible proton pumps", "antagonism of H2 histamine receptors", "pharmacologically effective amounts", "delayed release and/or extended release", and "rapidly released". The claims cover all dosage forms having these properties and all methods for the production of dosage forms having these properties, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such dosage forms and methods.

Independent of the above reasoning, the claims 1-39 also lack clarity (Article 6 PCT). An attempt is made to define the products by reference to a result to be achieved. This lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Specifically, the terms "acid susceptible proton pump inhibitor" and "H2 receptor antagonist" apparently relate to a very large amount of different compounds, which do not necessarily have to be defined as acid susceptible proton pump inhibitors or H2 receptor antagonists, thus rendering it impossible to perform a complete search.

Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely the present claim 2 in combination with the present claim 4, as well as the present claim 37 in combination with the present claim 38.